REMARKS/ARGUMENTS

Claims 1-9 are pending, claim 7 having been withdrawn from consideration. By this Amendment, claim 1 is amended. Support for the amendments to claim 1 can be found, for example, in original claim 1. No new matter is added. In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

Personal Interview

Applicants appreciate the courtesies extended to Applicants' representative by Examiners Fernandez and Lankford during the October 7, 2008 Personal Interview. Applicants' separate record of the substance of the interview is incorporated in the following remarks.

Rejection Under 35 U.S.C. §112, First Paragraph

The Office Action rejects claims 1-6, 8 and 9 under the written description requirement of 35 U.S.C. §112, first paragraph. Applicants respectfully traverse the rejection.

The Office Action asserts that the recitation of "the at least one oxidized starch and the at least one cellulose compound are chemically bonded to one another" in claim 1 is not supported by the present specification. As indicated in the previous response, support for the above-quoted feature can be found in the Declaration Under 37 C.F.R. §1.132 ("Declaration") filed on January 14, 2008, which demonstrates that chemical bonding between oxidized starches and cellulose is inherent in the disclosure of the present application. *See* Declaration, paragraphs 9 to 14.

The Office Action asserts that the Declaration shows that hydroxypropylmethyl-cellulose forms a chemical bond with oxidized starch, but does not show that the other

cellulose compounds (hydroxypropylcellulose, hydroxyethylcellulose and carboxymethylcellulose) form a chemical bond with an oxidized starch. *See* Office Action, pages 2 to 3. Applicants submit that the Declaration clearly indicates that "under the conditions of the Examples disclosed in the specification of the above-captioned patent application that oxidized starch and cellulose inherently form a chemical bond." *See* Declaration, paragraph 9. The Declaration further indicates that "[a]n esterification reaction taking place between oxidized starch and cellulose (e.g., hydroxypropylmethyl cellulose) forms a strong chemical bond between the oxidized starch and the cellulose. *See* Declaration, paragraph 12. Such a reaction is common knowledge in the field of the condensation of macromolecules."

These foregoing assertions in the Declaration are in no way limited to hydroxypropyl-methylcellulose. Moreover, the Declaration plainly asserts that any cellulose disclosed in the present specification combined with an oxidized starch in the manner disclosed in the present specification would yield an oxidized starch chemically bonded to the cellulose. The Office Action has provided no good faith basis for doubting the assertions set forth in the Declaration. Applicants have provided a factual basis for their assertion that the feature of claim 1, "the at least one oxidized starch and the at least one cellulose compound are chemically bonded to one another," is inherently supported by the present specification.

As agreed during the Personal Interview, the Declaration will be given careful further consideration along with these written remarks.

Claims 2-6, 8 and 9 are rejected solely for their dependency from claim 1.

For the foregoing reasons, claims 1-6, 8 and 9 are fully supported by the specification as filed. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Rejection Under 35 U.S.C. §112, Second Paragraph

The Office Action rejects claims 1-6, 8 and 9 as indefinite under 35 U.S.C. §112, second paragraph. Applicants respectfully traverse the rejection.

By this Amendment, claim 1 is amended to obviate the rejection. Claims 2-6, 8 and 9 are rejected solely for their dependency from claim 1.

For the foregoing reasons, claims 1-17 are definite. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Rejection Under 35 U.S.C. §103

A. Xu and Ushimaru

The Office Action rejects claims 1, 4, 8 and 9 under 35 U.S.C. §103(a) over U.S. Patent No. 6,419,903 to Xu et al. ("Xu") in view of U.S. Patent No. 5,368,861 to Ushimaru et al. ("Ushimaru"). Applicants respectfully traverse the rejection.

Claim 1 recites "[a]n edible film, comprising: at least one oxidized starch ... at least one cellulose compound ... at least one active substance ... wherein: the at least one oxidized starch and the at least one cellulose compound are chemically bonded to one another; and the film is composed so that the film will dissolve within 10 seconds of contact with saliva" (emphasis added). Xu does not disclose or suggest such a film.

As conceded in the Office Action, Xu does not disclose or suggest a composition that includes an oxidized starch chemically bonded to a cellulose, as recited in claim 1. *See* Office Action, page 6. However, the Office Action asserts that it would have been obvious to modify the composition of Xu by replacing the pregelatinized starch of Xu with an oxidized starch, as employed in Ushimaru. *See* Office Action, page 6.

Xu is directed to "a rapidly dissolvable orally consumable film composition." *See, e.g.,* Xu, Abstract. As discussed previously and conceded in the Office Action, this rapidly

dissolvable film composition is formed using a pregelatinized starch. *See* Xu, column 4, lines 54-63. Ushimaru discloses a preparation including a rapid release portion and a sustained release portion. *See, e.g.,* Ushimaru, Abstract. The oxidized starch identified in the Office Action is employed in the sustained release portion of the preparation of Ushimaru. *See* Ushimaru, claim 2.

The Office Action's proposed modification involves replacing a component in a rapidly dissolvable film composition (the pregelatinized starch of Xu) with a component from a sustained release composition, i.e., a composition that is intended to dissolve slowly (the oxidized starch of Ushimaru). One of ordinary skill in the art simply would not have been motivated to do so.

As discussed during the personal interview, Applicants note that claim 1 does not merely require a cellulose compound and an oxidized starch, but also requires that the composition be capable of dissolving within 10 seconds of contacting saliva. That is, it is not enough that the disparate components of Xu and Ushimaru be combined, but those components must be combined to obtain an edible film that has the solubility required in claim 1. The Office Action provides no basis for expecting that such a composition would be obtained.

As is well-settled, a *prima facie* case of obviousness based on a proposed modification to a reference (e.g., replacing the pregelatinized starch of Xu with the oxidized starch of Ushimaru) will only stand if one of ordinary skill would have had a reasonable expectation of success upon making the modification. *See, e.g.,* MPEP §2143.02 (citing *In re Merck & Co., Inc.*, 800 F.2d 1091 (Fed. Cir. 1986)). The Office Action has failed to demonstrate that one of ordinary skill in the art would have had reason to expect that the components of Ushimaru could be incorporated into the rapidly dissolvable film composition of Xu, while retaining that composition's function.

As Xu and Ushimaru fail to disclose or suggest an edible film including at least one oxidized starch that is chemically bound to at least one cellulose compound that is capable of dissolving within 10 seconds of contact with saliva, Xu and Ushimaru fail to disclose or suggest each and every feature of claim 1.

As explained, claim 1 would not have been rendered obvious by Xu and Ushimaru. Claims 4, 8 and 9 depend from claim 1 and, thus, also would not have been rendered obvious Xu and Ushimaru. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

B. Xu, Ushimaru, Hata and Sharik

The Office Action rejects claims 1-6, 8 and 9 under 35 U.S.C. §103(a) over Xu in view of Ushimaru, U.S. Patent No. 4,345,032 to Hata ("Hata") and U.S. Patent No. 5,206,026 to Sharik ("Sharik"). Applicants respectfully traverse the rejection.

For the reasons discussed above, Xu and Ushimaru fail to disclose or suggest the film of claim 1. Hata is cited for its alleged disclosure of lactobacillus strains having the ability to deodorize foul breath. *See* Office Action, page 7. Sharik is cited for its alleged disclosure of films including film-forming polymers such as hydroxyethyl cellulose. *See* Office Action, page 7. However, as Hata and Sharik, like Xu and Ushimaru, fail to disclose or suggest an edible film including at least one oxidized starch that is chemically bound to at least one cellulose compound that is capable of dissolving within 10 seconds of contact with saliva, the combination of references cannot render claim 1 obvious.

As explained, claim 1 would not have been rendered obvious by Xu, Ushimaru, Hata and Sharik. Claims 2-6, 8 and 9 depend from claim 1 and, thus, also would not have been rendered obvious by Xu, Ushimaru, Hata and Sharik. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

For the foregoing reasons, Applicants submit that claims 1-9 are in condition for allowance. Prompt reconsideration and allowance are respectfully requested.

Respectfully submitted,

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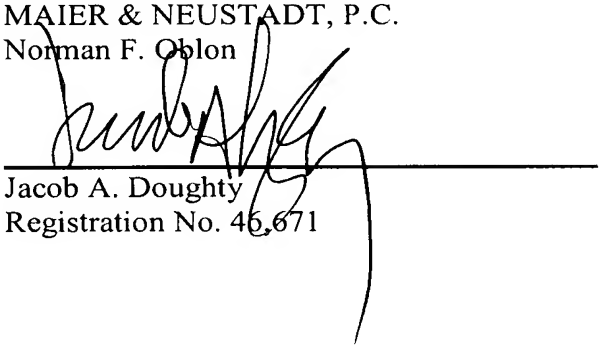
Norman F. Oblon



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